

**REMARKS / COMMENTS**

Reconsideration of the above-identified application is respectfully requested.

The present invention is a wound irrigation/fluid containment device having walls containing an inner and outer membrane from which is formed tubular inflatable chambers that provide structure to the containment device.

Claims of the application have been amended to restate the claims in a more definite format. No new matter has been added to the claims. The claims are patentable over the references.

Objections have been made to the drawings for not including adhesive means on for sealing the collar around the body part. Corrections of the drawings have been made and a revised drawing is submitted herewith.

The use of trademarks in the specification and claims has been noted by the examiner. The trademarks have been deleted in favor of generic terms.

**35 USC 112 REJECTIONS**

The claims have been rejected under section 112, second paragraph, for being indefinite for using certain terms, for example, "said end" in Claim 1 and "said collar" in Claims 10-11. The claims have been amended to delete the terms in question.

**35 USC 102(b) REJECTIONS**

Claims 1, 3-8 and 11 have been rejected under section 102(b) as being anticipated by the Fisher reference, U.S. Patent No. 5,316,541.

The examiner has described the Fisher reference as containing many elements of the claimed invention. In fact, a close reading of the reference shows otherwise. The structure and elements of the Fisher reference are divergent from the currently claimed

invention. The reference describes a tent for performing surgical procedures. It is not constructed to be a draining bag or even a readily usable surgical bag that can be fitted over a limb or body part. The tent is made of a flexible material that may collapse if not supported. Support structure 14 has a layer 40 which is sealed to the top and sidewalls of the tent forming an air-tight pocket 42. The pocket, when inflated, provides structural support for the tent. Plastic walls 25-28 are sheets of plastic and are not double-layered. Support structure 14 is the only double-layered feature disclosed in the reference. See col. 6, lines 48-58:

Once the apertures are formed and the adhesive assembly 18 is secured, the two plastic sheets that are to form the left and right sides 26, 28 of the tent 12 are welded to the folded sheet with a seam pre-coating. Next, the remaining plastic sheet is welded to the left side 26, the top, 29, and the right side 28 of the tent 12 to form the double layer support structure 14.

Thus, the Fisher reference does not disclose a double-walled feature throughout its structure but only at the certain locations for forming support structure 14. Additionally, the support structure is formed by adding or welding an additional plastic sheet to the existing tent wall. In contrast, the currently claimed invention comprises walls with two flexible membranes. The walls also integrally form an inflatable tubular chamber from the same plastic membrane material. No additional plastic material is added to form the chamber which, when inflated, serves as structural support for the containment bag. This feature is currently claimed in the present application and distinguishes the claims from the Fisher reference.

The Fisher reference also shows an opening which is located at the bottom of the tent. The opening receives covered tray 56. The walls of the tent are secured around the tray. This structure hardly anticipates applicant's opening around a body part or

limb in the containment device as currently claimed. Since applicant's claimed invention is not taught within the Fisher reference, the anticipation rejection must be withdrawn.

### **35 USC 103 REJECTIONS**

Claims 2 and 10 have been rejected under section 103 as being obvious in view of the Fisher reference and the Greco reference, U.S. Patent No. 5,312,385. The Greco reference discloses a collapsible bag that encompasses a body part or limb in which a pulse irrigation nozzle can be utilized for cleaning wounds. The bag has a drainage port and is supported by inflatable ribbing disposed upon the structure. As described at Column 5, lines 38- Column 6, line 5 of the Greco reference, inflatable ribbing is disposed upon the bag but is not constructed of the same material as the synthetic material utilized to form the bag. Indeed, additional structural supports may be rigid plastic or metal ribbing. The ribbing or supports, whether they are inflated or made from rigid materials encircle the outside of the bag and are separate from it. Figure 3 clearly shows this feature. Further, the language used in the specification indicates the structural supports or ribbing are on the outside of the bag, for example, "support means 31 is to dispose inflatable ribbing disposed upon enclosure 30" at Column 6, lines 2-3. This passage refers to the ribbing being "disposed upon" or "on" the enclosure, thus in normal grammar usage, "disposed upon the enclosure" would mean being positioned on the outside of the enclosure and supporting the enclosure from the outside to keep it away from the body part being treated. At column 6, lines 7 to 9, it is stated, "Alternatively, plastic or metal ribbing can be disposed at various positions upon enclosure 30 to provide desired support." The same usage of "disposed upon" is present, meaning that the ribbing is placed on the outside of the enclosure. Moreover,

the Greco reference does not disclose the double-walled feature of the presently claimed invention, much less the showing that the ribbing can be made from the material comprising the walls. The currently claimed invention is clearly distinguished from the Greco structure, taken singly or in combination with the tent structure of the Fisher reference. Merely reciting that the use of a collar, or adhesive, and a drain for receiving fluids, all of which are teachings from the Greco reference and combining those with the teachings of the Fisher reference as directed by this rejection, cannot render obvious the claimed invention.

Claim 9 has been rejected under section 103 for being obvious over the Fisher reference in view of the Alcorn et al reference, U.S. Patent No. 5,107,859. The Alcorn reference discloses a fluid collection bag containing foam material of a specific shape placed around a fluid drainage port providing support if the sidewalls collapse. Using foam pieces is not equivalent or even suggests the use of dimpled surfaces on side walls. The dimpled surfaces allow for the drainage of fluids if the side walls collapse. The use of foam material cannot render obvious applicant's claimed invention. The dimpled surfaces do not provide support in the manner of the foam material and are not intended to provide that function, but serve strictly to drain fluids if the side walls touch each other. The addition of the teachings of the Alcorn reference to the Fisher reference is meaningless in view of the current claims. Therefore, the rejection should be withdrawn.

The remaining references cited but not applied add nothing to the rejections made by the examiner and do not negate the patentability of the claimed invention.

Figure 5 has been amended to show adhesive means so that the drawing is in accordance with Claim 11. In this instance, the adhesive means is adhesive tape 38a. There is also support in the specification at paragraph 28 for sealing arrangements for the collar, which includes adhesive means and tape. Paragraph 28 has been amended to include adhesive tape 38a. No new support matter has been introduced into the application.

It is therefore submitted that the presently claimed invention defines patentable subject matter and meets the requirements of 35 U.S. C. sections 112, 102 and 103. An early Notice of Allowance is respectfully requested.

Respectfully submitted,

  
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